K061176

AUG 11 2006

510(k) Summary

1. Applicant's Name and Address

Straumann USA (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0031
Contact Person: Elaine Alan
Regulatory Affairs

2. Name of the Device

Trade Name:	Straumann Dental Implants
Common Name:	Dental Implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

Straumann RN Dental Implants, originally cleared under K033922 and K030007
Straumann NN Implants, originally cleared under K010291 and K030007

4. Description of the Device

The Straumann Dental Implant with anodized neck is a minor modification of cleared Straumann Dental Implants. The implants with anodized neck are available in two neck sizes, RN diameter 4.8 mm and NN diameter 3.5 mm. The design of the modified implants is identical to the predicate implants. There is no change to the endosseous grit blasted, acid etched SLA surface.

5. Intended Use of the Device

There is no change to the intended use associated with the modification. The neck portion is anodized for esthetic purposes.

6. Basis for Substantial Equivalence

The subject implants are substantially equivalent to the previously cleared Straumann implants cleared in, K033922, K030007 and K010291. The intended use is identical to the predicate devices. The subject implants with anodized neck are intended for placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations.

The subject implants have the same material composition and the same endosseous surface treatment as previously cleared Straumann implants. In addition, the design of the implant is identical to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Institut Straumann AG
C/O Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K061176
Trade/Device Name: Straumann Anodized Neck Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 13, 2006
Received: July 14, 2006

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

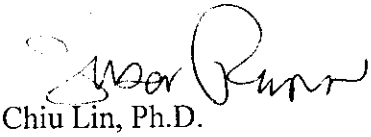
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061176

Device Name: Straumann Anodized Neck Implants

Indications for Use:

Straumann Regular Neck and Narrow Neck implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.

The Straumann Regular Neck Implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients for single-stage or two-stage surgery.

The Straumann Narrow Neck implants are intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the Narrow Neck implant is indicated for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibule-oral bone is restricted (minimum 5 mm). The Narrow Neck implant can also be used as a support for a full arch implant-born restoration, but only in conjunction with a standard Straumann 4.1 mm dental implant.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
) Number: K061176